EXHIBIT 4

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Motions, Pleadings and Filings

Only the Westlaw citation is currently available.

United States District Court, D. New Jersey.
ZENITH LABORATORIES, INC., Plaintiff,
v.
ABBOTT LABORATORIES, Defendant.
No. Civ.A. 96-1661.

Aug. 7, 1996.

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OPINION

BISSELL, J.

***1** This matter comes before the Court on a motion to dismiss and a motion for partial summary judgment. On April 15, 1996, plaintiff Zenith Laboratories, Inc. filed the instant complaint against defendant Abbott Laboratories. The complaint charges the defendant with unfair competition, abuse of process, tortious interference and fraud. It also seeks a declaratory judgment that plaintiff is not infringing defendant's relevant patents.

This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

FACTS AND BACKGROUND

The pharmaceutical industry is regulated by the Food and Drug Administration ("FDA"). The Federal Food, Drug and Cosmetic Act ("FFDCA") is the statute addressed to the manufacture and distribution of drugs and medical devices. *See* 21 U.S.C. § 301, *et seq.* New drug products, methods for employing those products and variations of the original drug may all receive individual patents. Once a drug is patented, it must receive FDA approval before it may be marketed in the United States. (*Id.*) The FFDCA sets out the specific requirements for obtaining marketing approval by the FDA. (*Id.*) However, in 1984, the FFDCA was amended by the Drug Price Competition and Patent Term Restoration Act, otherwise known as the "Hatch-Waxman Act," which modifies the necessary approval procedures. (Codified as amended at 21 U.S.C. § 355 (1994) and 35 U.S.C. § 271(d)--(h) (1995)).

The Hatch-Waxman Act provides for an abbreviated approval process for generic forms of previously approved pioneer drug products whose patents have or will soon expire or are proven invalid. A pharmaceutical company seeking approval to market a generic product must complete an Abbreviated New Drug Application ("ANDA"). The generic producer is excused from conducting the extensive clinical tests required for a New Drug Application ("NDA"). The ANDA applicant may rely upon the pioneer company's tests. It need only prove that the generic contains the same active ingredient as, and is bioequivalent to, the patented

drug.

Another significant difference made by the Hatch-Waxman Act is that the generic applicant may now use the patented drug to perform certain research and development without infringing the patent of the pioneer manufacturer. Prior to the amendment, the FFDCA provided:

> [W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

Accordingly, prior to the Hatch-Waxman Act, a producer of a generic product was required to wait until the pioneer drug went off patent before that producer could conduct the research and development necessary for FDA approval of a generic product. As a result, the patent owner was entitled to a *de facto* extension of the term of the patent, the duration of which was equivalent to the time the generic producer needed to research its proposed product and obtain FDA approval. The FFDCA now reads:

> ***2** It shall not be an act of infringement to make, use, or sell a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs....

35 U.S.C. § 271(e)(1). This provision is widely known as the "safe harbor" provision in that it permits otherwise infringing activity as long as it is reasonably related to obtaining regulatory approval for the generic drug product.

In the event the generic producer wishes to seek FDA approval during the term of the pioneer patent, the generic applicant must address each patent that claims the pioneer drug by including one of the following four certifications in its application:

1. that the pioneer has not filed patent information with the FDA,
2. that the patent has expired.
3. that the patent expires on a date before which the generic manufacturer is seeking to market its infringing equivalent, or
4. that the patent claiming the marketed pioneer drug is invalid or will not be infringed.

21 U.S.C. § 355(j)(2)(vii). If the generic applicant makes the fourth certification, it must provide notice of the certification to the patent owner and explain why the patent is invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(B). The Hatch-Waxman Act permits the patent owner to file a patent infringement action within 45 days of receipt of such notice. Prior to the Hatch-Waxman Act, preapproval patent infringement litigation was not available to the patent owner. The Act provides that infringement occurs if a generic manufacturer submits:

> an application under section 505(j) of the Federal Food, Drug and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent.

35 U.S.C. § 271(e)(2). Such a suit delays the approval of the generic product up to 30 months or until a judicial resolution of the infringement issues, whichever comes first. 21 U.S.C. § 355(j)(4)(B)(iii) . Once a "paragraph IV" certification is made and an infringement action filed, the issues of the validity and accuracy of the patent are resolved by the court, not the FDA.

The Hatch-Waxman Act benefits only those patent owners whose patents have been approved by the FDA for marketing. For approval, a patent owner is required to:

> file with the FDA the patent number and expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1). Once this information is received and the patent approved, it is published in a volume known as "Approved Drug Products With Therapeutic Equivalence Evaluations," which is commonly referred to as the "Orange Book." A patent is properly listed in the Orange Book if it claims an FDA-approved drug product and is a patent with respect to which a claim of infringement could reasonably be asserted. Zenith argues that Abbott has improperly listed patents in the Orange

Book by purporting that these patents claim the drug which is the subject of a pioneer patent with the purpose of invoking the Hatch-Waxman Act in order to keep Zenith out of the relevant market for up to 30 months and to subject it to sham patent infringement litigation.

***3** Abbott discovered and patented terazosin hydrochloride, which is used for the treatment of hypertension and benign prostatic hyperplasia. The '894 patent covers the compound itself and the '097 patent covers a specific composition and the method for treating hypertension with terazosin hydrochloride. Both of these patents have expired. The '532 patent covers a dihydrate form of terazosin hydrochloride, which is marketed by Abbott as "Hytrin." The '532 patent expires in May 1998. At the time they were issued, the above patents were listed in the FDA Orange Book. Other patents issued to Abbott, which Abbott claims are covered by the '532 patent, include the '176 patent, the '617 patent, the '095 patent and the '207 patent. These patents are all for anhydrous polymorphs of terazosin hydrochloride and differ from Hytrin only in their specific crystalline forms. They are all bioequivalent to Hytrin. These patents were listed in the Orange Book in 1994 and 1995.

Zenith intends to market a polymorph of terazosin hydrochloride, which is bioequivalent to "Hytrin." Zenith claims that its product has a different crystalline structure and therefore does not infringe the patent on Hytrin. On or about August 1, 1994, Zenith filed an ANDA with the FDA seeking permission to market its generic version of an anhydrous form of terazosin hydrochloride. At the time, Zenith made the required certifications, including one with respect to the '894 patent, which had expired, one with respect to the '097 patent which would expire prior to the date Zenith sought approval, and one with respect to the '532 patent, alleging that Zenith's product would not infringe that patent. Abbott did not file a patent infringement suit in response.

However, Abbott contends that Zenith's product infringes not the '532 patent, but its '615 patent which covers an anhydrous polymorph of terazosin hydrochloride. In 1994, Abbott filed a patent infringement suit, pursuant to the Hatch-Waxman Act, asserting that Zenith was infringing the '615 patent. At the time, the '615 patent was not listed in the FDA Orange Book and the suit was therefore dismissed for failure to state a claim. Shortly thereafter, Abbott listed the '615 patent in the Orange Book, claiming that it covered Hytrin, the subject of Abbott's '532 patent, and refiled its complaint. However, that action was also dismissed, this time on the grounds that the listing was untimely. The issue of whether the '615 patent was improperly listed or infringed has not yet been addressed.

In its complaint, Zenith contends that Abbott's listing of the '615, '176, ' 095 and '207 patents was improper. Specifically, Zenith argues that none of these patents are covered by Hytrin, an approved drug product, as they claim. Because the listing of a patent entitles a patent owner to the protections of the Hatch-Waxman Act, Zenith claims that Abbott, knowing the relevant patents are not covered by Hytrin, had them listed anyway for the purpose of forcing Zenith to make a paragraph IV certification, which then entitles Abbott to have delayed FDA approval of Zenith's generic product for up to 30 months by instituting a patent infringement suit against Zenith. The complaint asserts counts of unfair competition, abuse of process, tortious interference and fraud. It also seeks a declaration that its generic product does not infringe any of Abbott's patents.

ANALYSIS

I. Abbott's Motion to Dismiss is Denied

A. Standard for a Motion to Dismiss

***4** Fed.R.Civ.P. 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law. *Neitzke v. Williams,* 490 U.S. 319, 326 (1989) (citing *Hishon v. King & Spalding,* 467 U.S. 69, 73 (1984); *Conley v. Gibson,* 355 U.S. 41, 45-46 (1957). In disposing of a motion to dismiss, the court operates on the assumption that the factual allegations in the complaint or counterclaim are true. *Neitzke,* 490 U.S. at 326-27. A motion to

dismiss may be granted if the opposing party would not be entitled to relief under any set of facts consistent with the allegations in the complaint or counterclaim. As the Supreme Court stated in *Neitzke:*

> [n]othing in Rule 12(b)(6) confines its sweep to claims of law which are obviously insupportable. On the contrary, if as a matter of law "it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations," *Hishon, supra* at 73, 104 S.Ct. 2229, a claim must be dismissed, without regard to whether it is based on an outlandish legal theory or on a close but ultimately unavailing one. What Rule 23(b)(6) does not countenance are dismissals based on a judge's disbelief of a complaint's factual allegations.

(*Id.* at 327).

B. Zenith's Claims Arising Under State Law are not Preempted by the FFDCA.

Zenith's complaint charges Abbott with state law claims of unfair competition, abuse of process, tortious interference with prospective economic advantage and fraud. It also seeks a declaration of noninfringement. The conduct from which these claims arose is the alleged improper listing of Abbott's patents in the FDA Orange Book which, as Zenith claims, precipitated sham patent infringement litigation. Abbott contends these claims are preempted by the FFDCA and moves to dismiss the action.

Certain claims are expressly preempted by the FFDCA. However, the parties agree that the state law claims at issue are not among those expressly preempted. In the absence of an express statutory provision, state law is preempted only when the state law "actually conflicts with federal law" or "federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 523 (1992).

As an initial matter, it is persuasive that Congress expressly preempted state law claims pertaining to the safety of medical devices but did not expressly preempt any other claims. 21 U.S.C. § 360k(a). Such limited preemption leads to a reasonable inference that Congress intended to preempt only those claims specifically enumerated within the statute and for those not listed to remain viable. *Cipollone,* 505 U.S. at 517.

That the FFDCA is a comprehensive piece of legislation does not imply that it entirely occupies the regulated field.

> Preemption does not follow immediately from the comprehensive federal regulation of prescription biological products. Every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law.

***5** *Abbot by Abbot v. American Cyanamid,* 844 F.2d 1108, 1112 (4th Cir.1988). Furthermore, the state laws that regulate competition in the marketplace and the FFDCA are not in conflict and easily coexist. The goal of the FFDCA is the protection of public health. Common law claims such as those asserted here address wrongful business practices. It simply cannot be said that such state laws "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick,* 514 U.S. 280, 115 S.Ct. 1483, 1487 (1995). In addition, state claims of unfair competition and the like provide a remedy for conduct not addressed by the FFDCA which is the alleged improper listing of patents with the FDA.

Numerous courts considering the issue of preemption of those state laws that regulate the conduct of competitors in the marketplace have found that state law claims similar to those asserted in the underlying complaint are not preempted. *Michael v. Shiley, Inc.,* 46 F.3d 1316, 1329 (3d Cir.1995) (common law fraud claim asserted against a competitor not preempted); *Spychala v. G.D. Searle & Co.,* 705 F.Supp. 1024, 1029 (D.N.J.1988) (claims involving medical devices preempted, claims involving prescription drugs not preempted); *Hawkins v. Upjohn Co.,* 890 F.Supp. 609, 612 (E.D.Tex.1994) (fraud "and other general

torts" not preempted by the FFDCA). Furthermore, a violation of the FFDCA that gives rise to a separate cause of action does not necessarily lead to the conclusion that such a claim is preempted. *Reese v. Payless Drug Stores Northwest, Inc.*, 40 Cal.Rptr.2d 75 (Ct.App.1995) (unfair competition not preempted). State law claims that do not hinge upon the validity or infringement of a patent are not preempted. *Cover v. Hydramatic Packing Co.*, 89 F.3d 1390 (Fed.Cir.1996). The instant state law claims involve the question of whether the defendant has attempted to invoke the provisions of the Hatch-Waxman Act to gain an unfair competitive advantage. For the reasons stated above, this Court concludes that the FFDCA does not preempt plaintiff's state law claims relating to alleged unlawful business practices.

C. Zenith's State Law claims are Sufficient to Withstand a 12(b)(6) Motion.

It must be remembered that on a motion to dismiss the complaint, "the plaintiff is afforded the safeguard of having all its allegations taken as true and all inferences favorable to plaintiff will be drawn." *Westinghouse Elec. Corp. v. Franklin,* 789 F.Supp. 1313, 1317 (D.N.J.1992) *rev'd on other grounds,* 993 F.2d 349 (3d Cir.1993). A claim of unfair competition is one directed toward an entity that does not play fair, one who disparages or wrongfully captures the trade of another. *American Shops, Inc. v. American Fashion Shops of Journal Square, Inc.,* 13 N.J.Super. 416, 420-21 (App.Div.1951). Unfair competition encompasses an actionable infringement of a property right, "i.e., the right to pursue one's business, calling or occupation free from undue interference or molestation." *Kamm v. Flink,* 113 N.J.L. 582, 586 (E. & A.1934).

***6** In Count One, Zenith claims that Abbott has unfairly and unlawfully sought to obstruct competition in the market for terazosin hydrochloride by causing allegedly improper listings in the FDA Orange Book and instituting sham litigations against Zenith. New Jersey law provides:

> If a competitor ... engages in fraud ... or misrepresents, or threatens civil ... actions, or violates the law, then the competition is considered to be outside of permissible parameters, and liability will ensue.

C.R. Bard v. Wordtronics Corp., 235 N.J.Super. 168, 174 (Law Div.1989). Assuming the allegations in the complaint are true and considering that federal law does not preempt this claim, this Court determines that Zenith has articulated a claim of unfair competition against Abbott. [FN1] However, whether Zenith will ultimately prevail on such a claim is, at this time, far from clear.

> FN1. This Court notes that Abbott's contention that the claim of unfair competition should be dismissed on the grounds that Zenith has not suffered any injury is unfounded. In the event that Abbott's conduct is ultimately determined to constitute unfair competition, Zenith has already had to defend against two "bogus" lawsuits for patent infringement. That money damages are not yet quantifiable is irrelevant.

2. Abuse of Process

In Count Two, Zenith claims that the two prior lawsuits initiated by Abbott for patent infringement were improper and therefore an abuse of process. To prevail on a claim for abuse of process, the plaintiff must demonstrate an existence of an ulterior motive or purpose and some act in the use of legal process not proper in the regular prosecution of the proceedings. *Harris Custom Builders, Inc. v. Hoffmeyer,* 834 F.Supp. 256, 263 (N.D.Ill.1993). Zenith claims that Abbott has filed patent infringement actions against it, knowing that those actions were meritless and with the purpose of attempting to keep Zenith out of the terazosin hydrochloride market for 30 months when Abbott knew it was not entitled to such an extension on its exclusive position in the pharmaceutical industry. Like Zenith's claim for unfair competition, the claim for abuse of process claim is sufficiently stated to withstand a motion to dismiss.

3. Tortious Interference with Prospective

Economic Advantage

Count Three charges Abbott with tortious interference with Zenith's prospective economic advantage. The claimed economic advantage is that which Zenith expected to gain from the approval and marketing of its generic product. To prevail on such a claim, Zenith must establish that it had a reasonable expectation of economic benefit and that the defendant knowingly interfered with a benefit that had a reasonable likelihood of accruing to the plaintiff. *Fineman v. Armstrong World Indus., Inc.,* 980 F.2d 171, 186 (3d Cir.1992). The complaint charges Abbott with the knowledge that its '615 patent was improperly listed and the meritless pursuit of a patent infringement action with the purpose of keeping Zenith out of the terazosin hydrochloride market. Had Abbott's patent not been improperly listed, assuming for the instant purposes that it was, Zenith's generic product had a reasonable likelihood of approval without the statutory 30 month waiting period. Accordingly, Zenith has stated a claim for tortious interference with prospective economic advantage.

4. Fraud

***7** Count Four charges Abbott with common law fraud. In order to state such a claim, plaintiff must allege: (1) defendant made a material factual misrepresentation to plaintiff; (2) with the knowledge or belief of its falsity; (3) with the intention that plaintiff rely upon the representation; and (4) that plaintiff justifiably relied upon the misrepresentation to its detriment. *Agathos v. Starlite Motel,* 977 F.2d 1500, 1508 (3d Cir.1992). The fraud alleged to have occurred is Abbott's representation that it would use the samples of Zenith's generic product submitted to it by Zenith for the sole purpose of characterizing and identifying the terazosin hydrochloride in the generic product. (Letter dated Sept. 15, 1994, Exh. A). Zenith argues that Abbott received the samples, knowing the product could not infringe its '532 patent, with the intent of using those samples for the separate purpose of subjecting the compound to x-ray diffraction tests, which purpose was vastly beyond the scope of what was necessary to determine whether the '532 patent was infringed. (Letter dated Sept. 22, 1994). Even if these promises of Abbott are considered half-truths, New Jersey courts hold:

> A half-truth may be as misleading as a statement which is wholly false. A fraudulent misrepresentation may inhere in a statement which is truthful so far as it goes but which is materially misleading because of the failure to recite qualifying matters. The intentional concealment of material information is tantamount to an affirmative misrepresentation of the nonexistence of such information.

Medivox Productions, Inc. v. Hoffman-LaRoche, Inc., 107 N.J.Super. 47, 69- 70 (Law Div.1969). Accordingly, this Court concludes that Zenith has adequately alleged a claim of common law fraud.

C. Zenith has Adequately Pled a Claim for a Declaratory Judgment.

Zenith's fifth count seeks a declaratory judgment that its generic form of terazosin hydrochloride does not infringe any of Abbott's relevant terazosin hydrochloride patents. Zenith also seeks a declaration that the '615, '176, ' 095 and '207 patents are improperly listed in the FDA Orange Book in that none of those patents are covered by Abbott's Hytrin product and an order requiring Abbott to delist those patents.

For this Court to assert jurisdiction over Zenith's declaratory judgment claim, Zenith must have a reasonable apprehension of suit and have made meaningful preparation to commit acts Abbott would likely contest as infringing of its patents. *DuPont Merck Pharmaceutical v. Bristol-Myers Squibb,* 62 F.3d 1397, 1401 (Fed.Cir.1995). Both elements are satisfied. Zenith is in a position to begin marketing immediately its generic product after FDA approval. In addition, Abbott has twice filed patent infringement suits against Zenith with respect to its generic of terazosin hydrochloride and has also filed similar suits against other potential marketers of terazosin hydrochloride. (Rocco Del., ¶¶ 3, 8, 14). This history of litigation regarding alleged infringement of Abbott's terazosin hydrochloride patents is a clear indication that,

should Zenith seek approval of its generic product and make a "paragraph IV" certification that Abbott's patent is invalid, Zenith will be sued by Abbott for patent infringement, which suit would delay the marketing of the generic product for up to 30 months. *DuPont,* 62 F.3d at 1400-1401 (holding the fear of an infringement suit in response to a "paragraph IV" certification was within that required to establish jurisdiction over a claim for a declaratory judgment); *Infinitech, Inc. v. Vitrophage, Inc.,* 842 F.Supp. 332, 337-38 (N.D.Ill.1994) (public interest in the development and marketing of new medical products favors the adjudication of a declaratory judgment action prior to the expiration of a patent in the event the patent may be invalid and undeserving of a full term). As Zenith has demonstrated that a controversy exists and that a declaratory judgment of noninfringement would not conflict with the purposes of the statutory system, this Court concludes that it has jurisdiction over Zenith's claim for a declaratory judgment. This Court also concludes that, having met the requirements for a declaratory judgment, plaintiff has satisfied the necessary jurisdictional showing regardless of the fact that the FFDCA does not expressly provide for a private right of action. it is not an action under the FFDCA plaintiff seeks to pursue but under the Declaratory Judgment and All Writs Acts and state law. [FN2]

> FN2. In fact, the Northern District of Illinois, in considering other listings of Abbott in the FDA Orange Book, entertained a request for a declaratory judgment and, having found those listings to be improper, ordered Abbott to remove those listed patents from the Orange Book. *Abbott Lab. v. Geneva Pharms.,* Civ. No. 95 C 6657 (N.D.Ill. Apr. 9, 1996) (Mentlik Decl., Exh. 20).

II. Zenith's Motion for Partial Summary Judgment is Denied.

A. Standard for a Motion for Summary Judgment

***8** Federal Rule of Civil Procedure 56(c) provides that summary judgment should be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c); *see also Chipollini v. Spencer Gifts, Inc.,* 814 F.2d 893, 896 (3d Cir.) (*en banc*), *cert. dismissed,* 483 U.S. 1052 (1987). In deciding a motion for summary judgment, a court must view the facts in the light most favorable to the nonmoving party and must resolve any reasonable doubt as to the existence of a genuine issue of fact against the moving party. *Continental Insurance Co. v. Bodie,* 682 F.2d 436, 438 (3d Cir.1982). The moving party has the burden of establishing that there exists no genuine issue of material fact. *See Celotex Corp. v. Catrett,* 477 U.S. 317 (1986).

The Supreme Court has stated that, in applying the criteria for granting summary judgment,

> the judge must ask ... not whether ... the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented. The mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmoving party]. The judge's inquiry, therefore, unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the [non-movant] is entitled to a verdict....

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). A fact is "material" only if it will affect the outcome of a lawsuit under the applicable law, and a dispute over a material fact is "genuine" if the evidence is such that a reasonable fact finder could return a verdict for the nonmoving party. (*Id.*)

In order to survive a motion for summary judgment, an opposing party must present "more than a mere scintilla of evidence" in his favor. He "cannot simply reallege factually unsupported allegations contained in his pleadings." *Anderson v. Liberty Lobby,* 477 U.S. 242, 249, 325 (1986); *see also Maguire v. Hughes Aircraft Corp.,* 912 F.2d 67, 72 (3d Cir.1990). Only evidence that would be

admissible at trial may be used to test a summary judgment motion. Evidence with a deficient foundation must be excluded from consideration. *Williams v. Borough of West Chester, PA,* 891 F.2d 458, 466 (3d Cir.1989); *see also Trap Rock Indus., Inc. v. Local 825, Int'l Union of Operating Eng'rs,* 982 F.2d 884, 890-91 (3d Cir.1992).

B. The Instant Case

Zenith moves for summary judgment on the issue of whether the listing of Abbott's '176, '615, '095 and '207 patents was improper. In the event this Court were to make such a finding, Zenith asks for the entry of an order directing Abbott to delist those patents. Zenith argues that those patents are improperly listed because, although they claim Hytrin, none of them is actually covered by the Hytrin patent. Abbott disputes this and contends that its patents are covered by Hytrin. As Hytrin covers a dihydrate form of terazosin hydrochloride and the subsequent patents were issued for different anhydrous polymorphs of terazosin hydrochloride, which for the FDA's purposes are allegedly the same, Abbott submits that the contested patents properly claim Hytrin and that the listing of those patents in the FDA Orange Book was correct.

***9** Title 21 U.S.C. § 355 sets out the requirements for the listing of drug patents in the FDA Orange Book:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 335(b)(1). The following regulation has been implemented by the FDA to facilitate compliance with § 355:

> For patents that claim a drug substance or a drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product.

21 C.F.R. § 314.53(b). A listed drug is that which is also defined as approved for safety and effectiveness under § 355(c). 21 U.S.C. §§ 355(j)(2)(A) and (6)(A)(ii). Accordingly, the FDA approves for listing only those patents covered by an approved drug product. Therefore, if Abbott's patents are covered by Hytrin, which is an approved drug product, listing is appropriate.

As an initial matter, the FDA approved Abbott's '176, '615, '095 and '207 patents for listing. Such approval demonstrates that the FDA believed that those patents are covered by an approved drug product. The drug product that the FDA agreed covered the contested patents is, as those patents claim and Abbott submits, Hytrin. Both parties cite *Pfizer, Inc. v. FDA* in support of their arguments. 753 F.Supp. 171 (D.Md.1990). In *Pfizer,* the FDA refused to list a patent that failed to claim an approved drug product. Specifically, Pfizer had an approved patent which claimed nifedipine solution in an oral release capsule. It then sought to have approved a patent on a tablet formulation of nifedipine. As the tablet patent did not claim the FDA-approved oral release capsule, the FDA refused to approve the tablet formulation of nifedipine. [FN3] However, the patents at issue in the instant case do not claim an unapproved drug product, they claim the FDA-approved drug product of Hytrin.

> FN3. Although not discussed in the papers, it would seem that the purpose behind the requirement that a patent for which approval is sought must claim an approved drug product is that it allows the FDA to rely on the testing results of the previously-approved drug product in approving the patent that is the subject of the second application. In other words, if a patent for which approval is sought claims an approved drug product, the later patent may be approved on a more expedited basis because the FDA can rely on the tests performed on the previously-approved patent. This is essential because, where the later patent claims an approved drug

> product, it is considered the bioequivalent of that product. If a patent for which approval is sought fails to claim an approved drug product, it would likely be required to submit to lengthy and stringent safety and efficacy tests.

Zenith argues that, although the FDA found that the patents are covered by Hytrin, which must be undisputed as the FDA approved and listed each of the contested patents, this does not necessarily mean that the patents are actually covered by, or claim, Hytrin. [FN4] Hytrin and the four patents at issue all have different crystalline formulations. As such, Zenith contends that one anhydrous polymorph is not covered by a different anhydrous polymorph. If this argument is correct, one anhydrous polymorph would not be covered by a different yet FDA-approved, anhydrous polymorph, and could therefore not be listed without its own safety and efficacy testing.

> FN4. The FDA admits that it does not have the resources to examine whether a patent is properly listed after listing takes place. If a listing is contested, the FDA requires the patent owner to certify that the listing is appropriate or to voluntarily cause the patent to be delisted. 21 C.F.R. § 314.53(f) . Unless the patent owner changes the information submitted to the FDA, the FDA will not amend the Orange Book listing. (*Id.*) Abbott has certified that the listings are valid and refuses to delist its patents.

The crux of this motion for partial summary judgment on the issue of improperly listed patents is what a subsequent patent must claim to be appropriate for listing. Must the patent claim only an approved drug product or must it claim both the approved drug product and, in the case of an anhydrous polymorph, its exact crystalline structure. Abbott argues that, because Hytrin, a dihydrate form of terazosin hydrochloride, is the drug product covered in the relevant patent, the subsequent patents need only claim the drug substance claimed in Hytrin. As the relevant patents were issued with respect to anhydrous polymorph of Hytrin, which differ only in crystalline structure, Abbott submits that they are covered by Hytrin.

***10** The C.F.R. provides:

> For patents that claim a drug substance or a drug product, *the applicant shall submit information only on those patents* that claim a drug product that is the subject of a[n] ... approved application, or *that claim a drug substance that is a component of such a product.*

21 C.F.R. § 314.53(b). This Court reads this section to mean that if a patent claims the drug substance, or active ingredient, of an approved drug product, that patent is covered by the approved drug product and may be approved for marketing by the FDA and listed in the Orange Book.

The issue then becomes what is the relevant drug substance claimed by Hytrin and do the later Abbott patents claim that substance so that listing would be appropriate. Zenith argues that the relevant drug substance is the specific dihydrate form of terazosin hydrochloride, which is an anhydrous polymorph of terazosin hydrochloride. It argues that other crystalline forms of terazosin hydrochloride Abbott has patented do not claim the specific polymorph found in Hytrin. However, Abbott contends that the relevant drug substance is a general hydrated form of terazosin hydrochloride, and not the specific dihydrate formulation of that drug. In other words, Abbott argues that any patent on an anhydrous polymorph is covered by Hytrin as Hytrin claims a hydrated form, of the active ingredient and not the chemical make-up of that formulation.

The FDA provides that "anhydrous and hydrated entities are considered pharmaceutical equivalents." (Orange Book at xii, Coleman Decl., Exh. B). Pharmaceutical equivalents contain the same active ingredient. (*Id.*, at vii). They differ in "shape, scoring configuration, packaging, excipients (including colors, flavors, preservatives), expiration time, and, within certain limits, labeling." (*Id.*) The FDA has indicated that, as a general matter, "different polymorphic forms of the same drug substance (are the same) drug substances unless the differences in physical structure found in the

polymorphs result in inequivalent safety and efficacy profiles." (FDA Response to Citizen Petition of Janssen Pharmaceuticals, Coleman Decl., Exh. C at 4). The FDA also considers "differences in waters of hydration resulting in polymorphic crystal forms of the same active moiety (*i.e.,* different forms of the same active ingredient) to be the same when dissolution, solubility, and absorption are shown to be equivalent." (Letter from the Center for Drug Evaluation and Research, Coleman Decl., Exh. D at 4).

The contested patents are for different anhydrous polymorphs of terazosin hydrochloride. As stated above, different polymorphic forms containing the same active ingredient may be considered by the FDA as equivalents. However, this is the case only if the dissolution, solubility and absorption of the polymorphs are the same. It is not clear that these factors are consistent as between Hytrin and the later patents. Accordingly, a question of fact exists as to whether the later Abbott polymorphs are covered by Hytrin. There is simply not enough undisputed information before this Court for it to decide under the summary judgment standard whether a dihydrate version of terazosin hydrochloride covers anhydrous polymorphs that differ only in crystalline structure. In the event these polymorphs do have the same dissolution, solubility and absorption as that found within the drug substance in Hytrin, their patents would likely be construed as properly claiming the drug substance in Hytrin and the listing of those patents would be correct. However, if these polymorphs are found not to claim the drug substance in Hytrin, they could not likely claim to be covered by that drug substance and would then not be entitled to listing in the Orange Book. Those issues cannot presently be resolved summarily. Accordingly, Zenith's motion for partial summary judgment is denied.

CONCLUSION

***11** For the foregoing reasons, defendant's motion to dismiss is denied, and plaintiff's motion for partial summary judgment is also denied.

ORDER

For the reasons set forth in the Court's Opinion filed herewith,

It is on this 5th day of August, 1996

ORDERED that defendant's motion to dismiss plaintiff's complaint be, and it hereby is, denied; and it is further

ORDERED that plaintiff's motion for partial summary judgment be, and it hereby is, denied.

Not Reported in F.Supp., 1996 WL 33344963 (D.N.J.)

Motions, Pleadings and Filings (Back to top)

- 2:96CV01661 (Docket) (Apr. 15, 1996)

END OF DOCUMENT

EXHIBIT 5

21 U.S.C.A. § 332

Effective: [See Text Amendments]

United States Code Annotated Currentness
Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
Subchapter III. Prohibited Acts and Penalties

§ 332. Injunction proceedings

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown [FN1] to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

(b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

CREDIT(S)

(June 25, 1938, c. 675, § 302, 52 Stat. 1043; Oct. 10, 1962, Pub.L. 87-781, Title I, § 103(d), Title II, § 201(c), 76 Stat. 784, 793; Aug. 13, 1993, Pub.L. 103-80, § 3(d), 107 Stat. 775.)

[FN1] So in original. Probably should have a comma.

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1962 Acts. Senate Report No. 1744 and Conference Report No. 2526, see 1962 U.S. Code Cong. and Adm. News, p. 2884.

Amendments

1993 Amendments. Subsec. (a). Pub.L. 103-80, § 3(d)(1), struck out reference to the provisions of section 381 of Title 28 relating to notice to opposite parties.

Subsec. (b). Pub.L. 103-80, § 3(d)(2), struck out sentence which had required that the trial be conducted in accordance with the practice and procedures applicable in proceedings subject to the provisions of section 387 of Title 28.

1962 Amendments. Subsec. (a). Pub.L. 87-781 eliminated references to subsecs. (e) and (f) of § 331 of this title.

Effective and Applicability Provisions

21 U.S.C.A. § 332

1962 Acts. Section 203 of Pub.L. 87-781 provided that: "The amendments made by this title [amending section 374 of this title, eliminating "(f)" from subsec. (a) of this section, and enacting provisions set out as notes under §§ 321 and 374 of this title] shall take effect on the date of enactment of this Act [Oct. 10, 1962]."

Amendment of subsec. (a) by Pub.L. 87-781, which eliminated "(e),", effective on the first day of the seventh calendar month following Oct. 1962, see § 107 of Pub.L. 87-781, set out as a note under § 321 of this title.

1938 Acts. Section effective twelve months after June 25, 1938, see § 902(a) of Act June 25, 1938, set out as a note under § 392 of this title.

LAW REVIEW COMMENTARIES

An exercise in administrative creativity: The FDA's assertion of jurisdiction over tobacco. 45 Cath.U.L.Rev. 991 (1996).

Anchors away: The Food and Drug Administration's use of disgorgement abandons legal moorings. William W. Vodra and Arthur N. Levine, 59 Food & Drug L.J. 1 (2004).

From dog food to prescription drug advertising: Litigating false scientific establishment claims under the Lanham Act. Charles J. Walsh and Marc S. Klein, 22 Seton Hall L.Rev. 389 (1992).

LIBRARY REFERENCES

American Digest System

Drugs and Narcotics ⚿23.

Corpus Juris Secundum

CJS Drugs and Narcotics § 85, Injunction; Recalls.

CJS Drugs and Narcotics § 86, Proceedings.

CJS Drugs and Narcotics § 87, Violation.

RESEARCH REFERENCES

ALR Library

127 ALR, Fed. 141, What is "Drug" Within Meaning of § 201(G)(1) of Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 321(G)(1)).

13 ALR, Fed. 747, Regulation of Health Devices Under Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301 et seq.) as Affected by Religious Guaranties of First Amendment.

138 ALR, Fed. 393, What Matters Not Contained in Pleadings May be Considered in Ruling on a Motion to Dismiss Under Rule 12(B)(6) of the Federal Rules of Civil Procedure or Motion for Judgment on the Pleadings Under Rule 12(C) Without...

Encyclopedias

21 U.S.C.A. § 332

9 Am. Jur. Trials 59, Food Seizure Litigation.

25 Am. Jur. 2d Drugs and Controlled Substances § 209, Federal Food, Drug, and Cosmetic Act.

Forms

Federal Procedural Forms § 15:176, Enforcement, Generally.

Federal Procedural Forms § 31:193, Motion-For Temporary Restraining Order-To Prevent Commencement of Civil or Criminal Proceedings With Respect to Regulated Product (Fed R Civ P Rule 65).

Federal Procedural Forms § 31:195, Order-Granting Motion for Temporary Restraining Order in Declaratory Judgment Action as to Regulated Product (Fed R Civ P Rule 65(D)).

Federal Procedural Forms § 31:196, Motion and Notice-For Preliminary Injunction Prohibiting FDA from Taking Action Against Regulated Product Pending Outcome of Declaratory Judgment Proceeding (Fed R Civ P Rules 7(B) , 57, 65(a)).

Federal Procedural Forms § 31:197, Scope of Division.

Federal Procedural Forms § 31:199, Procedural Guide-In General.

Federal Procedural Forms § 31:200, Injunctions.

Am. Jur. Pl. & Pr. Forms Food § 34, Motion-For Temporary Restraining Order-To Prevent Commencement of Civil or Criminal Proceedings With Respect to Regulated Food Product.

Am. Jur. Pl. & Pr. Forms Food § 36, Order-Granting Motion for Temporary Restraining Order in Declaratory Judgment Action as to Regulated Food Product.

Am. Jur. Pl. & Pr. Forms Food § 37, Motion and Notice-For Preliminary Injunction Prohibiting FDA from Taking Action Against Regulated Food Product Pending Outcome of Declaratory Judgment Proceeding.

Treatises and Practice Aids

Federal Procedure, Lawyers Edition § 35:406, Jurisdiction.

Federal Procedure, Lawyers Edition § 35:407, Appropriateness of Injunctive Relief.

Federal Procedure, Lawyers Edition § 35:413, Contempt Proceedings.

Patent Law Fundamentals § 5:5, Cognate Types of Marks -- Certification Marks.

Wright & Miller: Federal Prac. & Proc. § 8078, Subdivision (E)-Rules Applicable in Part.

NOTES OF DECISIONS

1. Construction with other laws

Reference to "section 387 of Title 28" in subsec. (b) of this section serves to invoke section 3691 of Title 18 dealing with granting of a jury trial on demand of alleged contemnor, as well as provision of section 402 of Title 18 governing limitation on fines and imprisonment, but does not serve to invoke provision of section 402 of Title 18 excluding contempts committed in disobedience of decrees entered in suits brought in name or behalf of the United States; accordingly, proceeding wherein the United States sought an order to show cause why individual and corporate defendants should not be punished for contempt of preliminary and permanent injunctions enjoining interstate traffic in misbranded drugs was not subject to dismissal for want of jurisdiction. U. S. v. Diapulse Corp. of America, E.D.N.Y.1973, 365 F.Supp. 935. Federal Civil Procedure ⇦ 1742(2)

Subsection (b) of this section providing that former § 387 of Title 28 should be the procedure to be followed in prosecution of contempts for violation of injunctions procured under this section, merely established a limited special procedure to be followed in such cases, taking them out of the procedure generally followed in cases wherein injunction was procured by United States, but it did not place criminal contempt proceedings for violation

of injunctions procured by United States under this section within the purview of all provisions of former §§ 386-390a of Title 28. U. S. v. Dean Rubber Mfg. Co., W.D.Mo.1947, 72 F.Supp. 819. Injunction ⚿ 230(1)

2. Discretion of court

Where the device had been found to be generally misbranded in violation of this chapter and jury of laymen had found 49 specific claims to be false or misleading yet defendant continued its advertising scheme and it did not prove machine's effectiveness or relabel it to the Food and Drug Administration's satisfaction, injunction against defendant from shipping the device in interstate commerce until labeling met standards of this chapter to the satisfaction of Food and Drug Administration was not an abuse of discretion. U. S. v. Diapulse Corp. of America, C.A.2 (N.Y.) 1972, 457 F.2d 25. Health ⚿ 327

Matter of issuance of injunction is in broadest sense for discretion of trial court which is best qualified to form judgment as to likelihood of repetition of offense. U. S. v. Article of Drug Designated B-Complex Cholinos Capsules, C.A.3 (N.J.) 1966, 362 F.2d 923. Injunction ⚿ 1

District court did not abuse its discretion in issuing injunction restraining claimant drug company from any act which would result in products under seizure or similar products being introduced in interstate commerce as misbranded in manner found violative of this chapter notwithstanding that claimant's business relationship with radio broadcaster who endorsed products had terminated before issuance of injunction. U. S. v. Article of Drug Designated B-Complex Cholinos Capsules, C.A.3 (N.J.) 1966, 362 F.2d 923. Injunction ⚿ 22

Courts are reluctant to issue orders at preliminary stage of litigation regarding violations of this chapter where effect may be to eliminate the party as a competitive economic unit. U. S. v. C. E. B. Products, Inc., N.D.Ill.1974, 380 F.Supp. 664. Health ⚿ 328

3. Elements of proof

Government was not required to show irreparable injury to obtain an injunction against sale and movement of wheat from grain elevators found to be in violation of the food contamination and adulteration standards of the Food, Drug, and Cosmetic Act; district court should have presumed that Government would suffer irreparable injury from denial of its motion. U.S. v. Odessa Union Warehouse Co-op, C.A.9 (Wash.) 1987, 833 F.2d 172. Injunction ⚿ 138.72

No specific or immediate showing of precise way in which violation of law would result in public harm is required to support court's granting injunctive relief under this section. U. S. v. Diapulse Corp. of America, C.A.2 (N.Y.) 1972, 457 F.2d 25. Health ⚿ 327

In suit to enjoin the introduction into interstate commerce of allegedly misbranded drugs that were represented to cure cancer in some instances, it was not necessary for the Government to prove that each and every representation in booklet issued by those who sold the drugs was false or misleading. U.S. v. Hoxsey Cancer Clinic, C.A.5 (Tex.) 1952, 198 F.2d 273, certiorari denied 73 S.Ct. 496, 344 U.S. 928, 97 L.Ed. 714, rehearing denied 73 S.Ct. 642, 345 U.S. 914, 97 L.Ed. 1348, certiorari denied 74 S.Ct. 220, 346 U.S. 897, 98 L.Ed. 398. Injunction ⚿ 126

Government only needed to show violation and reasonable chance of recurring violations of Food, Drug, and Cosmetic Act in order to obtain permanent injunction. U.S. v. Vital Health Products, Ltd., E.D.Wis.1992, 786 F.Supp. 761, affirmed 985 F.2d 563. Health ⚿ 327

Provision which restrained persons from violating Food, Drug, and Cosmetic Act was satisfied where statutory conditions for relief were met; no additional showing was required for injunction to issue. U.S. v. 22 Rectangular or Cylindrical Finished Devices, More or Less, * * * the Ster-O-Lizer MD-200 * * *, Halogenic Products Co.,

21 U.S.C.A. § 332

D.Utah 1989, 714 F.Supp. 1159. Health ⚿ 327

Proof that drug manufacturer's products present a significant health hazard to the public is unnecessary for injunctive relief under this chapter. U. S. v. Medwick Laboratories, Inc., N.D.Ill.1976, 416 F.Supp. 832. Health ⚿ 327

The government was not precluded from restraining violation of this chapter, in introducing misbranded drugs into interstate commerce, on theory that government did not point out that particular formulas were harmful, where it was assumed by all witnesses that precise formulas were in controversy, and government's testimony disclosed that constituents of the formulas were harmful unless prescribed after a careful diagnosis of patient's troubles. U. S. v. Paddock, W.D.Mo.1946, 68 F.Supp. 407. Injunction ⚿ 128(8)

The government, to enjoin shipment of adulterated bakery products in interstate commerce, is not required to prove that products were injurious to health. U.S. v. Lazere, N.D.Iowa 1944, 56 F.Supp. 730. Injunction ⚿ 89(2)

4. Jurisdiction

This section did not confer jurisdiction over action brought against Hawaii's pineapple growers, dairy farmers, dairy processors, State of Hawaii and the United States for declaratory and injunctive relief against contamination of dairy products with pesticide heptachlor where plaintiff was private party suing in his own name. Fiedler v. Clark, C.A.9 (Hawai'i) 1983, 714 F.2d 77. Federal Courts ⚿ 192

District court properly exercised jurisdiction to enjoin distribution of certain veterinary drugs despite contention that, as a matter of primary jurisdiction, the Food and Drug Administration was required to conduct full hearings and conclude that the drugs involved were "new drugs" under section 360b of this title before seeking an injunction, where case presented purely legal question of interpretation of grandfather clause. U. S. v. Western Serum Co., Inc., C.A.9 (Ariz.) 1982, 666 F.2d 335. Health ⚿ 327

District court exceeded its authority in ordering that the Administration defer further regulatory action against pharmaceutical company and its product, since district court lacked jurisdiction to enjoin multiple seizure actions instituted by the Administration under this chapter. U. S. v. Alcon Laboratories, C.A.1 (Puerto Rico) 1981, 636 F.2d 876, certiorari denied 101 S.Ct. 3005, 451 U.S. 1017, 69 L.Ed.2d 388. Health ⚿ 332

District court had jurisdiction to consider the "new drug" status of amygdalin for purposes of the enforcement proceeding brought before it seeking to restrain manufacture and distribution of drug alleged to be misbranded and adulterated, despite contention that only the Food and Drug Administration has jurisdiction to determine in the first instance whether an article is a "new drug." U. S. v. Mosinee Research Corp., C.A.7 (Wis.) 1978, 583 F.2d 930. Health ⚿ 323

Drug manufacturer's use of components shipped in interstate commerce to make vitamin K for injection brought its activities within this chapter, and conferred jurisdiction to restrain violations thereof upon the district court. U. S. v. Dianovin Pharmaceuticals, Inc., C.A.1 (Puerto Rico) 1973, 475 F.2d 100, certiorari denied 94 S.Ct. 60, 414 U.S. 830, 38 L.Ed.2d 65. Health ⚿ 327

District courts are given jurisdiction to restrain violations of this chapter and legislative goals are the framework within which the court operates in deciding whether to grant relief. U. S. v. Diapulse Corp. of America, C.A.2 (N.Y.) 1972, 457 F.2d 25. Health ⚿ 327

In suit to enjoin interstate traffic in misbranded drugs, where complaint alleged sales in interstate commerce but no purchaser was named as a party and United States did not sue as representative of any purchaser, district court did not have jurisdiction to order restitution by directing payment of money to United States. U. S. v. Parkinson, C.A.9

21 U.S.C.A. § 332

(Cal.) 1956, 240 F.2d 918. Health ⚿ 327

Where federal district court by legal service of process on defendants obtained personal jurisdiction over defendants in suit for injunction under this section, such jurisdiction, once obtained, could not be terminated by alleged fraud of the officers and agents of the Food and Drug Administration. Reich v. U.S., C.A.1 (Me.) 1956, 239 F.2d 134, certiorari denied 77 S.Ct. 563, 352 U.S. 1004, 1 L.Ed.2d 549. Federal Courts ⚿ 26.1; Courts ⚿ 30

The jurisdiction of district court under this section is limited to restraining the introduction or delivery for introduction into interstate commerce of products that are adulterated or misbranded. Hygrade Food Products Corp. v. U.S., C.C.A.8 (Iowa) 1947, 160 F.2d 816. Injunction ⚿ 110

District court has power to enjoin present and future violations of this chapter solely on basis that a violation has been established, such as marketing of a "new drug" without proper preclearance. U.S. v. Premo Pharmaceutical Laboratories, Inc., D.C.N.J.1981, 511 F.Supp. 958. Health ⚿ 327

Given the interrelation between complaint's first and second counts, the first seeking seizure and condemnation against certain articles of food or drug containing amygdalin, commonly known as Laetrile, and the second seeking preliminary injunctive relief against the manufacturers of such articles of food or drug to restrain alleged violations of this chapter; the district court, while it might technically have jurisdiction to make a final ruling on the merits of the first count, would refrain from doing so pending a decision by the court of appeals on an appeal taken from the district court's ruling in the second count. U. S. v. Articles of Food and Drug, E.D.Wis.1977, 444 F.Supp. 266. Federal Courts ⚿ 682

5. Amendment of pleadings

No prejudice was shown from trial court's allowing complaint to be amended to state prayer for injunctive relief after jury had returned its verdict in proceeding for forfeiture of drugs. U. S. v. An Article of Drug, C.A.9 (Cal.) 1981, 661 F.2d 742. Federal Courts ⚿ 894

Government's proposed amendment, sought after plenary trial was held, that decision rendered in its favor, under this chapter, to include prayer for injunctive relief would be granted where respondent had not been prejudiced, there was no adequate reason to preclude government from obtaining such relief, and illegal conduct complained of was likely to continue unless enjoined. U. S. v. 47 Bottles, More or Less, Jenasol RJ Formula '60', D.C.N.J.1962, 201 F.Supp. 915, affirmed in part, reversed in part on other grounds 320 F.2d 564, certiorari denied 84 S.Ct. 444, 375 U.S. 953, 11 L.Ed.2d 313. Health ⚿ 332

In proceeding in rem for condemnation of allegedly adulterated dried whole eggs, amendment of pleading to include a prayer for injunction against claimant would be allowed where prayer for condemnation and prayer for injunction both grew out of same transaction and basic issues were identical. U. S. v. 184 Barrels Dried Whole Eggs, E.D.Wis.1943, 53 F.Supp. 652. Injunction ⚿ 26(4); Federal Civil Procedure ⚿ 84.1

6. Defenses--Good faith

Defendant could not complain that injunction granted against it under this section, was impermissible because it would put him out of business. U. S. v. Diapulse Corp. of America, C.A.2 (N.Y.) 1972, 457 F.2d 25. Health ⚿ 327

The good faith or charitable intentions of defendant are no defense to suit to enjoin the introduction of misbranded drugs into interstate commerce in violation of this chapter. U. S. v. Hoxsey Cancer Clinic, N.D.Tex.1950, 94

21 U.S.C.A. § 332

F.Supp. 464, reversed on other grounds 198 F.2d 273, certiorari denied 73 S.Ct. 496, 344 U.S. 928, 97 L.Ed. 714, rehearing denied 73 S.Ct. 642, 345 U.S. 914, 97 L.Ed. 1348, certiorari denied 74 S.Ct. 220, 346 U.S. 897, 98 L.Ed. 398. Injunction 109

In suit to enjoin introduction of allegedly misbranded drugs into interstate commerce, the exemptions provided in § 353 of this title, with reference to physicians' prescriptions and the placing of contents on container, were inapplicable and of no avail to defendants, where defendants' method and treatment being used by physicians to whom drugs were sent were not so displayed. U. S. v. Hoxsey Cancer Clinic, N.D.Tex.1950, 94 F.Supp. 464, reversed on other grounds 198 F.2d 273, certiorari denied 73 S.Ct. 496, 344 U.S. 928, 97 L.Ed. 714, rehearing denied 73 S.Ct. 642, 345 U.S. 914, 97 L.Ed. 1348, certiorari denied 74 S.Ct. 220, 346 U.S. 897, 98 L.Ed. 398. Health 313

Injunctive relief against introduction of misbranded drugs into interstate commerce will not be denied on ground of discontinuance of the practice. U. S. v. Hoxsey Cancer Clinic, N.D.Tex.1950, 94 F.Supp. 464, reversed on other grounds 198 F.2d 273, certiorari denied 73 S.Ct. 496, 344 U.S. 928, 97 L.Ed. 714, rehearing denied 73 S.Ct. 642, 345 U.S. 914, 97 L.Ed. 1348, certiorari denied 74 S.Ct. 220, 346 U.S. 897, 98 L.Ed. 398. Injunction 109

7. ---- Cessation of activities, defenses

Cessation of activities either before or after suits is begun does not in itself bar issuance of injunction. U. S. v. Article of Drug Designated B-Complex Cholinos Capsules, C.A.3 (N.J.) 1966, 362 F.2d 923. Injunction 22

Claim by defendants that they are ready to cease violating this chapter does not bar issuance of injunction particularly where cessation arises only as result of official pressure or threatened litigation. U. S. v. Sene X Eleemosynary Corp., Inc., S.D.Fla.1979, 479 F.Supp. 970. Health 327

Not even the complete cessation of alleged violations of this chapter will, of itself, afford ground for denying injunctive relief. U. S. v. Medwick Laboratories, Inc., N.D.Ill.1976, 416 F.Supp. 832. Health 327

Attempt by drug manufacturer to correct past departures from good manufacturing practices by taking steps to make changes and improvements in those processes was not ground for denial of temporary restraining order under this chapter. U. S. v. Medwick Laboratories, Inc., N.D.Ill.1976, 416 F.Supp. 832. Health 328

Injunction could issue if it was reasonable to expect that defendants would commit violative acts in future, despite discontinuance of such illegal conduct at time injunction was sought. U. S. v. Sars of Louisiana, Inc., E.D.La.1971, 324 F.Supp. 307. Injunction 22

Issuance of injunction, which would avoid multiplicity of suits, preventing drug manufacturer and president from introduction into interstate commerce of drug, the labeling of which had been determined to be condemned by this chapter, could not be held inequitable or contrary to settled law where danger of recurrent violation by defendants was not in dispute. U. S. v. Nysco Laboratories, Inc., E.D.N.Y.1963, 215 F.Supp. 87, affirmed 318 F.2d 817. Health 327

Injunction may be granted even after illegal conduct has ceased. U. S. v. 47 Bottles, More or Less, Jenasol RJ Formula '60', D.C.N.J. 1962, 201 F.Supp. 915, affirmed in part, reversed in part on other grounds 320 F.2d 564, certiorari denied 84 S.Ct. 444, 375 U.S. 953, 11 L.Ed.2d 313. Injunction 22

A temporary injunction against shipment in interstate commerce of adulterated bakery products prepared under insanitary conditions and containing filthy substance would not be denied because defendant was doing best he could under circumstances. U.S. v. Lazere, N.D.Iowa 1944, 56 F.Supp. 730. Injunction 138.72

21 U.S.C.A. § 332

8. Res judicata

Determination, in in rem proceedings under this chapter that labeling of product was condemned by this chapter supporting judgment denying claim for return but allowing stay pending final disposition of appeal res judicata as to drug company defendant therein in government's subsequent action against it and its president for injunction, against introduction of drug involved in interstate commerce, under misbranding provisions of this chapter, though appeal in the in rem cases had not been disposed of. U. S. v. Nysco Laboratories, Inc., E.D.N.Y.1963, 215 F.Supp. 87, affirmed 318 F.2d 817. Judgment ⚿ 663

Any determination in condemnation proceeding under this chapter is res judicata in subsequent injunction action against claimant under misbranding provisions of this chapter. U. S. v. 216 Bottles, More or Less, Sudden Change by Lanolin Plus Lab. Div. Hazel Bishop Inc., E.D.N.Y.1965, 36 F.R.D. 695. Judgment ⚿ 646

9. Restraining orders

Where neither party to action by Government to enjoin drug manufacturer from violating this chapter attempted to separate the bad practices from those which might be good, the temporary restraining order would cover all products identified by the complaint until the parties had had an opportunity for further hearings or agreements. U. S. v. Medwick Laboratories, Inc., N.D.Ill.1976, 416 F.Supp. 832. Health ⚿ 327

10. Preliminary injunctions

Relief granted by preliminary injunction restraining continued violations of this chapter in the manufacture and distribution of Laetrile was not too broad, since the Government had made a sufficient showing of continued violations and the preliminary injunction was reasonably directed to prohibition of such violations. U. S. v. Mosinee Research Corp., C.A.7 (Wis.) 1978, 583 F.2d 930. Health ⚿ 328

Under evidence before trial court in action to enjoin distribution of allegedly misbranded drug, including evidence that literature which accompanied drug contained false and exaggerated claims, indicating every probability that government would prevail at trial, and evidence that defendants might not be able to meet refund claims, trial court did not abuse discretion in issuing preliminary injunction. U. S. v. Wilson Williams, Inc., C.A.2 (N.Y.) 1960, 277 F.2d 535. Injunction ⚿ 147

United States was entitled to preliminary injunction prohibiting pharmaceutical company defendants from violating Food, Drug and Cosmetic Act (FDCA) and mail fraud statute; there was a substantial likelihood government would succeed on merits of its claims that company defendants were violating the FDCA by marketing and promoting its botulinum toxin product for human use knowing that the Food and Drug Administration (FDA) had not approved it for human use, that the product distributed by the defendants was misbranded in that it lacked adequate directions for use, that defendants had made materially false, fictitious, or fraudulent statements or representations in a matter within the jurisdiction of the government of the United States, and that defendants would continue to violate the statutes unless enjoined. U.S. v. Livdahl, S.D.Fla.2005, 356 F.Supp.2d 1289. Injunction ⚿ 102

Where corporation engaged in production and distribution of cheese had made no apparent efforts to perform testing for presence of foreign substances in cheese and did not improve unsanitary conditions since first being notified of them by Food and Drug Administration (FDA) inspectors, injunction to prevent introduction or delivery for introduction into interstate commerce of food from corporation was appropriate until proper sanitary conditions were restored. U.S. v. Union Cheese Co., N.D.Ohio 1995, 902 F.Supp. 778. Injunction ⚿ 89(2)

Preliminary injunctions based on violations of statute prohibiting introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded do not require showing of immediate and irreparable injury. U.S. v. Barr Laboratories, Inc., D.N.J.1993, 812 F.Supp. 458.

21 U.S.C.A. § 332

Health ⚿ 328

Under Federal Food, Drug and Cosmetic Act, remedy of injunction is available to contradict manufacturer and distribution of imitation drugs. U.S. v. Articles of Drug, D.C.Neb.1984, 601 F.Supp. 392. Health ⚿ 327

Since defendant's generic drugs, although having same active ingredients as those approved in their FDA-approved pioneer counterpart, qualified as "new drugs" within meaning of section 321 of this title, marketing thereof without proper preclearance violated section 355 of this title and manufacturer would be preliminarily enjoined from shipping such drugs in interstate commerce and from manufacturing, processing, packing, and labeling any new drugs after shipment of their components in interstate commerce unless the drugs were approved by FDA or are used in investigations in compliance with applicable regulations. U.S. v. Premo Pharmaceutical Laboratories, Inc., D.C.N.J.1981, 511 F.Supp. 958. Health ⚿ 319; Health ⚿ 328

Preliminary injunction would be issued barring introduction into interstate commerce of, misbranding, or promotion of "GH-3," in view of fact that it was new drug for which there was no approved new drug application and in view of fact that it had been misbranded. U. S. v. Sene X Eleemosynary Corp., Inc., S.D.Fla.1979, 479 F.Supp. 970. Health ⚿ 328

Since genuine issues of material fact existed with respect to sterility and quality of devices for use in human eyes, precluding finding that Government had reasonable likelihood of prevailing on the merits of its claim that those devices violated this chapter, preliminary injunction pendente lite would not be issued as to distribution or manufacture of those devices. U.S. v. K-N Enterprises, Inc., N.D.Ill.1978, 461 F.Supp. 988. Health ⚿ 328

Although defendants, against whom preliminary injunction was issued with respect to violations of this chapter, were essentially put out of business by injunctive decree prohibiting manufacture or distribution in interstate commerce of articles of food or drug containing amygdalin, this was a permissible form of relief in the preliminary injunctive decree since the benefit to public clearly outweighed harm to defendants and was necessary to prevent continued violations of this chapter. U. S. v. Articles of Food and Drug, E.D.Wis.1977, 441 F.Supp. 772. Health ⚿ 328

Where Government made preliminary showing that manufacturer of cosmetic article had violated provisions of section 331 of this title, prohibiting introduction into interstate commerce of an adulterated cosmetic and prohibiting any act with respect to a cosmetic while it is held for sale after shipment in interstate commerce resulting in article being adulterated, preliminary injunction would issue to prohibit manufacturer from introducing or delivering for introduction into interstate commerce cosmetic article which contained poisonous or deleterious substance of methyl methacrylate monomer and from manufacturing article from components shipped in interstate commerce resulting in article containing such substance. U. S. v. C. E. B. Products, Inc., N.D.Ill.1974, 380 F.Supp. 664. Health ⚿ 328

Where Government delayed 20 months in moving to reopen case under this chapter and to reinstate preliminary injunction that had been in force for over six years prior to dismissal, even though dismissal was technically inappropriate, injunction would not be reinstated since the facts forming the basis for the injunction bore no relation to the facts existing when motion to reinstate was filed and Government delayed its motion eight months after it became aware of the dismissal, but order of dismissal would be modified to make it "without prejudice" so that Government could proceed against more recent violations of law. U. S. v. Richlyn Laboratories, Inc., E.D.Pa.1973, 365 F.Supp. 805. Federal Civil Procedure ⚿ 1841

Court in proceeding under this chapter in which it found mislabeling, in granting preliminary injunction precluding labeling suggesting, implying, stating or representing stated things would not incorporate prohibition against use of specific pieces of literature. U. S. v. Vitasafe Corp., D.C.N.J.1964, 235 F.Supp. 84. Injunction ⚿ 157

21 U.S.C.A. § 332

Preliminary injunction following decree of condemnation in proceeding under this chapter directed against vitamin food supplement found mislabeled would be issued prohibiting defendants from, inter alia, distributing any labeling which suggested or implied that woman, because of sex alone, has different nutritional needs that nutritional value of product was enhanced by presence of certain ingredients, that minimum adult vitamin requirements were recommendation of stated agency, or representing or implying that large amounts of common foods would be needed to obtain quantities of nutrients present in one capsule of the food. U. S. v. Vitasafe Corp., D.C.N.J.1964, 235 F.Supp. 84. Health ⚿ 328

Government makes sufficient showing to warrant preliminary injunction under this chapter by presenting evidence of violations of this chapter; it is not necessary for the government to demonstrate precise way in which violations might result in injury to public interest, but it is sufficient to show only that threatened act is within declared prohibition of Congress. U. S. v. Nutrition Service, Inc., W.D.Pa.1964, 227 F.Supp. 375, affirmed 347 F.2d 233. Health ⚿ 328

It is sufficient to warrant preliminary injunction under this chapter to show that articles intended for use in diagnosis, cure, mitigation, treatment or prevention of diseases in man or articles intended to affect structure of any function of body of man or being distributed in violation of this chapter. U. S. v. Nutrition Service, Inc., W.D.Pa.1964, 227 F.Supp. 375, affirmed 347 F.2d 233. Health ⚿ 328

Where defendants advertised that oil sold by them in interstate commerce in both capsule and liquid form was a medicine to be used in treatment of psoriasis, eczema, leg sores, leg ulcers, and athlete's foot, directions that liquid form should be applied to affected parts morning and night, that for open sores cotton should be saturated with oil and bound on by gauze, that fresh dressings should be put on morning and night, and that for tender skin oil could be diluted 50 per cent with olive oil, and that capsules should be taken one a day at bed time and then, after three or four days, one capsule should be taken after each meal, were not adequate and the government was entitled to a preliminary injunction. U. S. v. Colgrove, S.D.Cal.1947, 83 F.Supp. 880. Health ⚿ 312; Injunction ⚿ 138.24

11. Stay of proceedings

District court's interlocutory order that the Administration defer further regulatory action against pharmaceutical company and one of its products was an injunction, since order had effect of forbidding the Administration from exercising in any forum its statutory power both to proceed against company and its product and to seize article pending condemnation; thus, Court of Appeals had jurisdiction to review order. U. S. v. Alcon Laboratories, C.A.1 (Puerto Rico) 1981, 636 F.2d 876, certiorari denied 101 S.Ct. 3005, 451 U.S. 1017, 69 L.Ed.2d 388. Federal Courts ⚿ 558

Court would not stay government's action to enjoin corporation and its president, under misbranding provisions of this chapter from introducing certain drug into interstate commerce, pending outcome of corporation's appeal from judgment, rendered in another district in in rem proceedings upon determination that labeling of drug was condemned by this chapter, denying corporation's claim for seized drugs. U. S. v. Nysco Laboratories, Inc., E.D.N.Y.1963, 215 F.Supp. 87, affirmed 318 F.2d 817. Action ⚿ 69(5)

12. Depositions and discovery

Protective order would not be granted by federal District Court in suit by United States to enjoin alleged violations of this chapter to prevent taking of depositions and production of documents while appeal to Court of Appeals was pending from preliminary injunction, on ground that discovery proceeding might be futile because there was possibility that Court of Appeals would make matter moot, where public interest, welfare, and health were matters of concern in litigation, and administrative agents were, in good faith, attempting to administer public health laws. U. S. v. Nutrition Service, Inc., W.D.Pa.1964, 234 F.Supp. 578, affirmed 347 F.2d 233. Federal Courts ⚿ 686

21 U.S.C.A. § 332

In action by United States to enjoin defendants from introducing into interstate commerce certain capsules containing phenylpropanolamine hydrochloride on ground that defendants were misbranding the drug, interrogatories concerning medical and scientific facts were proper to extent that they sought medical and scientific facts within knowledge or possession of defendants, but if medical and scientific facts were not within knowledge of defendants, they were required only to so state. U. S. v. Nysco Laboratories, Inc., E.D.N.Y.1960, 26 F.R.D. 159 . Federal Civil Procedure ⚿ 1513; Federal Civil Procedure ⚿ 1534

In action by United States to enjoin defendants from introducing into interstate commerce certain capsules containing phenylpropanolamine hydrochloride on ground that defendants were misbranding the drug, opinions of expert witnesses were proper subject of discovery, and certain interrogatories of the United States with respect thereto would be allowed, but defendants should not be required to analyze and summarize written opinions of expert witnesses but should be required only to describe and identify them. U. S. v. Nysco Laboratories, Inc., E.D.N.Y.1960, 26 F.R.D. 159. Federal Civil Procedure ⚿ 1513

In action by the government for an injunction to prevent the introduction in interstate commerce of an allegedly misbranded product claimed to be a dietary aid, there is nothing in this chapter that makes the usual discovery procedures inapplicable to such an injunction action. U.S. v. Wilson-Williams, Inc., S.D.N.Y.1959, 24 F.R.D. 468 . Federal Civil Procedure ⚿ 1

In action for an injunction to prevent introduction in interstate commerce of an allegedly misbranded product, usual discovery procedures were not rendered inapplicable to such an action on the ground that permitting the government to use such discovery procedures would circumvent the safeguards provided in § 373 of this title respecting immunity from prosecution to those persons required to permit copying of their records concerning interstate shipments, where the interrogatories requested did not ask for any information which if asked for from the government under § 373 of this title would furnish an immunity from criminal prosecution. U.S. v. Wilson-Williams, Inc., S.D.N.Y.1959, 24 F.R.D. 468. Federal Civil Procedure ⚿ 1514.1

13. Hearing

Food and Drug Administration is not required to conduct full administrative hearing before bringing an enforcement action to enjoin the marketing of adulterated new drugs, and court should limit its determination to whether the government has met its burden to demonstrate sufficient probable cause to believe that drug in question is a new drug; if government meets its burden, an injunction will issue. U. S. v. Western Serum Co., Inc., D.C.Ariz.1980, 498 F.Supp. 863, affirmed 666 F.2d 335. Health ⚿ 327

14. Jury trial

An action for an injunction against further distribution of a drug as a "misbranded" and unapproved "new drug" is purely equitable in nature, so that a jury trial on injunction alone would not be required under U.S.C.A. Const.Amend. 7. U.S. v. Articles of Drug Consisting of Following: 5,906 Boxes, C.A.1 (Puerto Rico) 1984, 745 F.2d 105, certiorari denied 105 S.Ct. 1358, 470 U.S. 1004, 84 L.Ed.2d 379.

Medical device company and its principal who were charged with criminal contempt based on their violation of court orders which enjoined them from committing acts relating and leading up to violations of Federal Food, Drug, and Cosmetic Act did not have statutory right to jury trial in connection with contempt proceedings; contemptuous acts did not independently constitute offense under Act. U.S. v. 22 Rectangular or Cylindrical Finished Devices, More or Less, STER-O-LIZER MD-200***...Halogenic Products Co., D.Utah 1996, 941 F.Supp. 1086, affirmed 140 F.3d 858. Jury ⚿ 24.5

15. Evidence--Admissibility

21 U.S.C.A. § 332

In government's action to restrain defendant from violations of this chapter, by sending misbranded drugs in interstate commerce, testimony that the years of defendant's treatment by mail had not been attended by complaints from patients or partrons was inadmissible. U. S. v. Paddock, W.D.Mo.1946, 68 F.Supp. 407. Injunction 127

16. ---- Weight and sufficiency, evidence

Manufacturer of medical device's insistence on justifying its actions in committing violation of medial device reporting (MDR) regulations is important factor in deciding whether future violations are sufficiently likely to warrant permanent injunction. U.S. v. Laerdal Mfg. Corp., C.A.9 (Or.) 1995, 73 F.3d 852. Health 327

Evidence of seriously deficient conditions and practices at drug manufacturer's plant, coupled with a history of unsuccessful efforts to obtain compliance by manufacturer with laws designed to protect health and lives of the public, more than warranted injunctive relief. U. S. v. Dianovin Pharmaceuticals, Inc., C.A.1 (Puerto Rico) 1973, 475 F.2d 100, certiorari denied 94 S.Ct. 60, 414 U.S. 830, 38 L.Ed.2d 65. Health 327

Portion of injunction enjoining manufacturer from shipping vitamins in interstate commerce when accompanied by labeling representing, inter alia, that nearly everyone in country was suffering from, or was in danger of suffering from, dietary deficiency of vitamins, minerals and proteins, which was likely to result in specific deficiency diseases, which was made without factfinding that any such representations had been formerly made or that they were false or misleading, was proper where basis for this part of injunction was amply established by record. U. S. v. Vitasafe Corp., C.A.3 (N.J.) 1965, 345 F.2d 864, certiorari denied 86 S.Ct. 290, 382 U.S. 918, 15 L.Ed.2d 232. Injunction 189

Evidence sustained finding that certain defendants were guilty of criminal contempt in violating injunction entered in action by the United States under this section. Reich v. U.S., C.A.1 (Me.) 1956, 239 F.2d 134, certiorari denied 77 S.Ct. 563, 352 U.S. 1004, 1 L.Ed.2d 549. Contempt 60(3); Injunction 230(3)

In suit to enjoin the introduction into interstate commerce of allegedly misbranded drugs that were represented to cure cancer in some instances, hearsay testimony of patients, who took the drugs, that they had been told by a physician that they were suffering from cancer was entitled to no weight. U.S. v. Hoxsey Cancer Clinic, C.A.5 (Tex.) 1952, 198 F.2d 273, certiorari denied 73 S.Ct. 496, 344 U.S. 928, 97 L.Ed. 714, rehearing denied 73 S.Ct. 642, 345 U.S. 914, 97 L.Ed. 1348, certiorari denied 74 S.Ct. 220, 346 U.S. 897, 98 L.Ed. 398. Evidence 314(2)

In suit to enjoin the introduction into interstate commerce of allegedly misbranded drugs that were represented to cure cancer in some instances, testimony of laymen that they had suffered from cancer and that the drugs cured cancer was not entitled to any weight. U.S. v. Hoxsey Cancer Clinic, C.A.5 (Tex.) 1952, 198 F.2d 273, certiorari denied 73 S.Ct. 496, 344 U.S. 928, 97 L.Ed. 714, rehearing denied 73 S.Ct. 642, 345 U.S. 914, 97 L.Ed. 1348, certiorari denied 74 S.Ct. 220, 346 U.S. 897, 98 L.Ed. 398. Evidence 568(1)

In suit to enjoin violations of § 352(f)(1) of this title, by introducing misbranded drugs into interstate commerce, evidence sustained finding that in view of promotional literature sent by defendant to prospective customers which contained claims, representations and suggestions for use of drugs not present on label, that labels did not bear adequate directions for use. Alberty Food Products v. U. S., C.A.9 (Cal.) 1952, 194 F.2d 463. Injunction 128(8)

In action by United States to enjoin defendants from introducing allegedly misbranded sex hormones into interstate commerce, evidence established that the hormones, including testosterone, were inherently dangerous and were not safe and efficacious for use except under supervision of a physician, and were not suitable for self-medication. U. S. v. El-O-Pathic Pharmacy, C.A.9 (Cal.) 1951, 192 F.2d 62. Injunction 128(3.1)

21 U.S.C.A. § 332

Although United States' expert in support of its position that manufacturer of automatic external defibrillators violated good manufacturing practices (GMP) regulations implementing Federal Food, Drug and Cosmetic Act was credible witness, weight that district court would give her testimony was necessarily limited because information that expert was given to rely upon was incomplete and because her review of procedures followed by manufacturer was limited. U.S. v. Laerdal Mfg. Corp., D.Or.1994, 853 F.Supp. 1219, affirmed 73 F.3d 852. Evidence 571(3)

Record in proceeding to adjudicate defendants in contempt for failure to comply with injunction order established that defendants had not complied with preliminary injunction by failing to list all distributors of amygdalin produced or distributed by defendants, by failing to list all places where defendants knew that any of their amygdalin or any component thereof was stored, and that two of the defendants had not forfeited to United States all existing amygdalin and amygdalin components in their possession or control, justifying adjudication of civil contempt. U. S. v. Articles of Food and Drug, E.D.Wis.1978, 449 F.Supp. 497. Injunction 230(3)

Evidence established that there was no reason to believe that defendants would commit in future acts violative of this chapter. U. S. v. Sars of Louisiana, Inc., E.D.La.1971, 324 F.Supp. 307. Injunction 128(8)

Evidence on government's preliminary injunction application under this chapter revealed that defendants' product derived from fermentation and molding process of natural components of wheat, yeast, salt and water, was distributed and dispensed in interstate commerce for cure, treatment, mitigation and prevention of diseases in man. U. S. v. Nutrition Service, Inc., W.D.Pa.1964, 227 F.Supp. 375, affirmed 347 F.2d 233. Health 328

Showings made on government's application under this chapter for preliminary injunction revealed that product derived from fermentation and molding process of natural components of wheat, yeast, salt and water, the labeling promotional literature and other written material concerning which had overall effect of indicating its use in cure, mitigation, treatment and prevention of cancer and other diseases constituted a "drug" and a "new drug" within this chapter. U. S. v. Nutrition Service, Inc., W.D.Pa.1964, 227 F.Supp. 375, affirmed 347 F.2d 233. Health 328

In proceeding under this chapter to enjoin introduction into interstate commerce of defendant's vaginal suppositories, evidence established that suppositories were misbranded, within meaning of § 352(a), (j) of this title, in that statements on label that drug was safe and effective treatment for minor vaginal irritations were false and misleading and in that drug was dangerous to health of user if taken in dosage and for duration prescribed. U. S. v. Grayce, Inc., N.D.Ind.1954, 126 F.Supp. 6. Injunction 128(8)

Evidence established that labeling and literature treated as labels on drugs introduced by defendant into interstate commerce constituted a misbranding of drugs entitling government to have defendant restrained from further introduction of such drugs in interstate commerce. U. S. v. Paddock, W.D.Mo.1946, 68 F.Supp. 407. Injunction 128(8)

Evidence was insufficient to entitle government to injunction preventing shipment in interstate commerce of egg powder on ground that the egg powder was adulterated because of decomposition. U. S. v. 184 Barrels Dried Whole Eggs, E.D.Wis.1943, 53 F.Supp. 652. Food 6; Injunction 128(8)

17. Findings

Federal judge who presided in action to enjoin shipment of allegedly misbranded drug, was entitled to rely on different judge's findings, in seizure suit between same parties, that defendant's representations were false and misleading. U. S. v. Nysco Laboratories, Inc., C.A.2 (N.Y.) 1963, 318 F.2d 817. Judgment 648

In suit to enjoin violations of § 352(f)(1) of this title by introducing misbranded drugs into interstate commerce, trial court properly took into consideration, in making its findings that drugs in question were misbranded,

promotional literature sent by defendant to prospective customers, which material contained claims, representations and suggestions relating to use of drugs not present on labels. Alberty Food Products v. U. S., C.A.9 (Cal.) 1952, 194 F.2d 463. Injunction ⚿ 130

Where evidence on appeal from judgment adverse to United States in action by United States to enjoin defendants from introducing certain allegedly misbranded drugs known as hormones into interstate commerce consisted solely of record in prior prosecution in which defendants were found guilty of distributing misbranded sex hormones, by trial judge sitting without a jury, and different judge tried injunction cases, findings of trial court would be given due consideration, and judgment would be reversed with reluctance, but findings were not entitled to weight, court of appeals would otherwise be obliged to concede to findings. U. S. v. El-O-Pathic Pharmacy, C.A.9 (Cal.) 1951, 192 F.2d 62. Federal Courts ⚿ 855.1

18. Summary judgment

In enforcement action instituted by the United States under this chapter, in which government sought to enjoin drug manufacturer from marketing "adulterated" drugs allegedly not manufactured in accordance with current good manufacturing practice, manufacturer failed to raise question of material fact either as to accuracy of special reports or as to whether such reports indicated current good manufacturing practice violations such as would preclude summary judgment for the government. U. S. v. Western Serum Co., Inc., D.C.Ariz.1980, 498 F.Supp. 863, affirmed 666 F.2d 335. Federal Civil Procedure ⚿ 2498.5

In suit to enjoin violations of this chapter by introducing misbranded drugs into interstate commerce, where facts established by pleadings, and pretrial stipulations demonstrated inadequacy of labels, Government was entitled to summary judgment restraining introduction of drugs into interstate commerce until they bore adequate directions for use. U. S. v. Alberty Food Products, S.D.Cal.1951, 98 F.Supp. 23, affirmed 194 F.2d 463. Federal Civil Procedure ⚿ 2498.5

19. Judgment

An injunction restraining processor of cheese and milk products from filthy milk from shipping any products in interstate commerce for two years was erroneous in not retaining jurisdiction for purpose of enforcing or modifying the judgment at any time and in denying processor the right to ship any products in interstate commerce irrespective of purity, instead of restraining only the acts forbidden by this chapter. Hygrade Food Products Corp. v. U.S., C.C.A.8 (Iowa) 1947, 160 F.2d 816. Injunction ⚿ 190

Where, since submission of government's action to restrain violations of this chapter, defendant died, but government was entitled at time case was tried to judgment or decree as prayed, in view of defendant's death a decree would be entered nunc pro tunc as of date case was submitted. U. S. v. Paddock, W.D.Mo.1946, 68 F.Supp. 407. Judgment ⚿ 273(5)

20. Recall

Voluntary nature of manufacturers' recall of candy which is suspected to be adulterated does not foreclose regulation by Federal Drug Administration respecting mandatory source coding and record keeping by manufacturers to expedite location and recall. National Confectioners Ass'n v. Califano, C.A.D.C.1978, 569 F.2d 690, 187 U.S.App.D.C. 35. Food ⚿ 5

Provision of this section vesting a district court of the United States with jurisdiction to "restrain violations" of this chapter does not authorize a district court to issue an order recalling drugs from the market place. U. S. v. Superpharm Corp., E.D.N.Y.1981, 530 F.Supp. 408. Health ⚿ 323

21 U.S.C.A. § 332

Although this chapter grants no specific authority to require recall of drugs in violation of its provisions, this section granting authority to district courts "to restrain violation" of section 331 of this title prohibiting introduction into interstate commerce of adulterated or misbranded drugs permits district court to grant affirmative or mandatory relief. U.S. v. K- N Enterprises, Inc., N.D.Ill.1978, 461 F.Supp. 988. Health 327

General equity jurisdiction of district court suffices for authority to order recall of drugs in violation of this chapter, since its provisions, by which jurisdiction is given over controversy involving drugs, does not preclude such relief. U.S. v. K-N Enterprises, Inc., N.D.Ill.1978, 461 F.Supp. 988. Health 327

Even if federal court had the authority under this chapter to order manufacturer of adulterated cosmetic product to recall cosmetic products sitting in warehouses and retail stores, where recall would render manufacturer insolvent and necessitate bankruptcy proceedings and where injuries suffered by consumers' using cosmetic product could be treated, court would not require manufacturer to recall product. U. S. v. C. E. B. Products, Inc., N.D.Ill.1974, 380 F.Supp. 664. Health 327

21. Grant of injunction

Injunction may be framed to bar future violations that are likely to occur, and decree which prohibited introduction of drug products into interstate commerce for any use was not too broad in view of facts that evidence was heard by judge as well as jury and that judge, not jury, determined scope of injunction based upon judge's view of facts established by the evidence. U. S. v. An Article of Drug, C.A.9 (Cal.) 1981, 661 F.2d 742. Health 327; Injunction 189

District court reasonably concluded that post-injunction sales of vitamin tablets might be the end product of prior misbranding, and properly enjoined such sales. U. S. v. Vitasafe Corp., C.A.3 (N.J.) 1965, 345 F.2d 864, certiorari denied 86 S.Ct. 290, 382 U.S. 918, 15 L.Ed.2d 232. Injunction 189

Under this section, district court could enjoin shipping in interstate commerce of products advertised as being beneficial in treatment of skin diseases, without a label containing adequate directions for their use in treatment of skin conditions for which they were prescribed, recommended and suggested in advertising material. Colgrove v. U.S., C.A.9 (Cal.) 1949, 176 F.2d 614, certiorari denied 70 S.Ct. 349, 338 U.S. 911, 94 L.Ed. 561. Injunction 89(2)

Where cheese and cheese products were processed by defendant from filthy milk, the defendant was properly enjoined from shipping products so processed in interstate commerce. Hygrade Food Products Corp. v. U.S., C.C.A.8 (Iowa) 1947, 160 F.2d 816. Injunction 89(2)

Dietary supplement distributor would be permanently enjoined from marketing products containing shark cartilage, rice bran and extract of sand brier, following determination that products were mislabeled under Food, Drug and Cosmetic Act (FDAC), regardless of whether future distribution would be accompanied by invalid health claims; severity of past false claims was so great that distributor might benefit from customers' recollection of those claims, unless there was total ban. U.S. v. Lane Labs-USA, Inc., D.N.J.2004, 324 F.Supp.2d 547, issued 324 F.Supp.2d 582, modified in part 328 F.Supp.2d 520. Health 327

Pharmaceutical manufacturer would be permanently enjoined from resuming manufacturing and shipping operations until Food and Drug Administration (FDA) found compliance with current "good manufacturing practices" regulations, even though regulations did not specify exact conditions which would be acceptable to FDA investigator, and would also be permanently enjoined from placing adulterated or misbranded drugs into interstate commerce; injunction was only available remedy which would protect public health and safety. U.S. v. Richlyn Laboratories, Inc., E.D.Pa.1993, 822 F.Supp. 268. Health 327

21 U.S.C.A. § 332

Fact that drug manufacturer intended to comply with current good manufacturing practice regulations before manufacturing of challenged drugs would be resumed did not bar district court from issuing an injunction to that effect. U. S. v. Western Serum Co., Inc., D.C.Ariz.1980, 498 F.Supp. 863, affirmed 666 F.2d 335. Health ⚿ 327

Where a case alleging violations of this chapter is in a preliminary stage and a full trial on the merits has not been conducted, a mandatory injunction should issue only if exceptional circumstances are present. U. S. v. C. E. B. Products, Inc., N.D.Ill.1974, 380 F.Supp. 664. Health ⚿ 328

Where manufacturer was guilty of manufacturing and selling products for control of obesity which were adulterated and misbranded, government was entitled to injunction against manufacturer's continued introducing of such products into interstate commerce. U. S. v. Lanpar Co., N.D.Tex.1968, 293 F.Supp. 147. Injunction⚿ 89(5)

Defendant was restrained from shipping in interstate commerce adulterated butter manufactured or to be manufactured in its Macon, Georgia, plant, where it appeared that butter manufactured in Georgia plant was "adulterated" within meaning of this chapter, in that it consisted in part of a filthy and decomposed substance and was unfit for food, and it did not appear that, under present conditions existing in Georgia cream industry, other and further adulterations could adequately be prevented by defendant, notwithstanding that defendant's plant itself was sanitary and its equipment was standard and satisfactory. U.S. v. Swift & Co., M.D.Ga.1943, 53 F.Supp. 1018 . Injunction ⚿ 89(2)

22. Form of injunction

Injunction prohibiting pharmaceutical company from selling, advertising, or marketing specified "look-alike" drug products was not overbroad, despite company's claim that injunction's requirement that buyers who purchased more than 5,000 dosage units certify they were engaged in lawful drug distribution prevented it from employing unobjectionable marketing techniques to sell otherwise legal products. U.S. v. Articles of Drug Consisting of Undetermined Quantities of Drugs Containing Caffeine, Ephedrine, Ephedrine Sulfate, Phenylpropanolamine HCL, Doxylamine Succinate, C.A.8 (Neb.) 1989, 890 F.2d 1004. Health ⚿ 327

Distributing same drugs under different names would not except them from injunction, nor would use of different labels, where injunction broadly prohibited introduction of products into interstate commerce for any use, without reference to labeling, and injunction was not fatally flawed because it referred to adulterated drugs by their trade names. U. S. v. An Article of Drug, C.A.9 (Cal.) 1981, 661 F.2d 742. Health ⚿ 327

Injunction under this section may sweep broadly in its prohibition if that is necessary to enjoin future violations which appear likely to occur. U. S. v. Diapulse Corp. of America, C.A.2 (N.Y.) 1972, 457 F.2d 25. Health⚿ 327

Injunction must be complete and sufficiently specific in itself to instruct enjoined party as to what acts are prohibited. U. S. v. Article of Drug Designated B-Complex Cholinos Capsules, C.A.3 (N.J.) 1966, 362 F.2d 923. Injunction ⚿ 204

Injunction prohibiting distribution of drugs if labeling failed to state "directions for use and all conditions for which such drug or devices prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer, packer, or distributor, or in such other conditions if any there be, for which such drug or devices commonly and effectively used, thereby resulting in said drugs being misbranded within the meaning of 21 U.S.C. 352(f)(1)" was to be modified by inclusion of words "sufficient information to enable a layman to intelligently and safely attempt self-medication without professional assistance" and by deletion of words "other conditions if any there be, for which such drug or device is commonly and effectively used". U. S. v. Article of Drug Designated B-Complex Cholinos Capsules, C.A.3 (N.J.) 1966, 362 F.2d

21 U.S.C.A. § 332

923. Injunction ⚿ 204

Portion of injunction attempting to enjoin sales of vitamin capsules to any person to whom manufacturer had previously sent, prior to date of decree, any written matter making specified false claims, irrespective of whether sale was end product of such written matter or result of solicitation by proper post-decree literature, was beyond permissible limits and must be vacated. U. S. v. Vitasafe Corp., C.A.3 (N.J.) 1965, 345 F.2d 864, certiorari denied 86 S.Ct. 290, 382 U.S. 918, 15 L.Ed.2d 232. Injunction ⚿ 189

Portion of injunction prohibiting distribution of literature which contained certain specified statements and misrepresentations, "or which is otherwise false and misleading", lacked required specificity as to the quoted clause, and such clause should be deleted from injunction. U. S. v. Vitasafe Corp., C.A.3 (N.J.) 1965, 345 F.2d 864, certiorari denied 86 S.Ct. 290, 382 U.S. 918, 15 L.Ed.2d 232. Injunction ⚿ 204

Language of injunctions with respect to which defendants were alleged to be in contempt and which prohibited deliveries in interstate commerce of Diapulse devices, assembled or unassembled, and of articles of device known as Diapulse, or any similar articles or devices, in whole or in part, assembled or unassembled, without prior approval of Food and Drug Administration was sufficient to comprehend deliveries of "modification kits" if they were for integration and operation of Diapulse units and were so described in accompanying literature as to extend quoted therapeutic claims to united devices. U. S. v. Diapulse Corp. of America, E.D.N.Y.1973, 365 F.Supp. 935. Health ⚿ 327

Part of proposed preliminary injunction that would direct defendants, who, through misbranding and adulterating drugs, had engaged in overt, long-standing, schematic and unpenitent thwarting of this chapter to operate their plant in conformity with "current good manufacturing practices" was not overbroad. U. S. v. Lit Drug Co., D.C.N.J.1971, 333 F.Supp. 990. Health ⚿ 328

Part of proposed preliminary injunction that would restrain drug manufacturer, which, through misbranding and adulterating drugs, had engaged in overt, long-standing, schematic and unpenitent thwarting of this chapter from engaging in interstate commerce until FDA officials had made thorough plant inspection of all equipment, materials, labels, containers and procedures and were satisfied that such were in compliance with current good manufacturing practices was authorized by this chapter. U. S. v. Lit Drug Co., D.C.N.J.1971, 333 F.Supp. 990. Health ⚿ 328

Part of proposed preliminary injunction that would restrain drug manufacturer, which, through misbranding and adulterating drugs, had engaged in overt, long-standing, schematic and unpenitent thwarting of this chapter from engaging in interstate commerce until FDA had opportunity to examine and assay all drugs presently being held at manufacturer's plant and to recall those assayed lots which proved to be adulterated was not harsh or punitive and was related to future production of drugs. U. S. v. Lit Drug Co., D.C.N.J.1971, 333 F.Supp. 990. Health ⚿ 328

23. Modification of injunction

District court, which had issued an interlocutory injunction in suit seeking liable of seizure and condemnation pursuant to section 334 of this title from which an appeal was taken, would not consider motion of defendants to modify decree which was filed at the same time as the notice of taking appeal from the interlocutory injunction where government opposed motion to modify and the motion went to the merits of decree before court of appeals. U. S. v. Articles of Food and Drug, E.D.Wis.1977, 441 F.Supp. 772. Federal Courts ⚿ 682

Although permanent injunction preventing owners of fish processing plant from processing fish that was "adulterated" within meaning of FDCA was appropriate, given owners' failure to dispute hazardous condition of plant, injunction would be altered, in light of apparent closure of plant, to eliminate ban on processing of fish products at locations other than closed plant. U.S. v. Blue Ribbon Smoked Fish, Inc., C.A.2 (N.Y.) 2003, 56

21 U.S.C.A. § 332

Fed.Appx. 542, 2003 WL 193719, Unreported. Injunction ⚿ 189

24. Reinstatement of injunction

In view of district court's prior findings that drugs were distributed, and components received, in interstate commerce, from which drug manufacturer did not appeal, and in view of consented-to order of permanent injunction which recited that the court "has jurisdiction of the subject matter herein and of all persons or parties hereto.", Government, on its motion to reinstate its earlier permanent injunction, which restrained manufacturer from activities violative of this chapter, for breach of conditions of its suspension, had no duty to reestablish interstate connections of drug which was complained of in original proceeding. U. S. v. Dianovin Pharmaceuticals, Inc., C.A.1 (Puerto Rico) 1973, 475 F.2d 100, certiorari denied 94 S.Ct. 60, 414 U.S. 830, 38 L.Ed.2d 65. Health ⚿ 327

25. Stay of injunction pending appeal

Defendants were not entitled to the stay of that paragraph of temporary injunction, from which appeal had been taken, restraining violations of this chapter and requiring defendants to disclose all distributors of amygdalin produced or distributed by defendants in all places where defendants had knowledge that any of their amygdalin or any component thereof is stored or held, since defendants could have no vested interest in a business found to be illegal, and whatever injury defendants might have suffered through disruption of business relationships was entitled to little weight. U. S. v. Articles of Food and Drug, E.D.Wis.1977, 441 F.Supp. 772. Federal Courts⚿ 685

Pending appeal of temporary injunctive order entered against defendants for violations of this chapter, provisions of decree relating to the sequestration of food or drug containing amygdalin found in possession of defendants, their officers, agents, servants and employees would not be stayed but that provision of paragraph relating to the destruction of such food or drug would be granted, since in event of success defendants would be irreparably harmed by destruction of their property while harm to government or public by granting a stay was not existent. U. S. v. Articles of Food and Drug, E.D.Wis.1977, 441 F.Supp. 772. Federal Courts ⚿ 685

Court would not stay those paragraphs of temporary injunction in proceeding under section 334 of this title relating to liable of seizure and condemnation that required defendants to compensate United States for cost of supervision of destruction of articles of food or drug involved by giving United States right to recover from defendants the cost of action whenever finally ascertained, since defendants would suffer no irreparable injury even if the provisions were overturned by the court of appeals. U. S. v. Articles of Food and Drug, E.D.Wis.1977, 441 F.Supp. 772. Federal Courts ⚿ 685

26. Contempt proceedings--Generally

One who was not a party to injunction suit under this chapter but who was mailed a copy of injunction when it was issued in the suit, and who read the injunction and knew its terms, was guilty of criminal contempt in violating the injunction. Reich v. U.S., C.A.1 (Me.) 1956, 239 F.2d 134, certiorari denied 77 S.Ct. 563, 352 U.S. 1004, 1 L.Ed.2d 549. Contempt ⚿ 29; Injunction ⚿ 228

To be guilty of violating § 331 of this title, it was not necessary that party be engaged in interstate commerce with respect to misbranded drug, but it was sufficient if he was engaged in delivering such drug for introduction into interstate commerce; and therefore, where application for order to show cause why party should not be prosecuted for criminal contempt for violation of injunction against violation of such section alleged that defendant had knowingly and regularly sold misbranded drugs and delivered them knowing that they were purchased for transportation in interstate commerce, and that he had solicited customers to return for future purchases and deliveries, application stated an offense. U. S. v. Sanders, C.A.10 (Okla.) 1952, 196 F.2d 895, certiorari denied 73

21 U.S.C.A. § 332

S.Ct. 33, 344 U.S. 829, 97 L.Ed. 645. Injunction ⚿ 230(2)

Advertisements addressing themselves to "skin sufferers" and referring indiscriminately not only to four diseases named on label of the products but also to other diseases "prescribed" the product for diseases other than those named on the label so as to violate an injunction prohibiting introduction of products into commerce without a label containing adequate directions for use in treatment of all conditions for which the products were "prescribed," recommended and suggested in advertising material and defendants were properly punished for contempt. Colgrove v. U.S., C.A.9 (Cal.) 1949, 176 F.2d 614, certiorari denied 70 S.Ct. 349, 338 U.S. 911, 94 L.Ed. 561. Injunction ⚿ 223

Proceeding wherein United States sought an order to show cause why defendants should not be punished for contempt of preliminary and permanent injunctions restraining interstate traffic in misbranded drugs would be transferred formally to criminal docket in order to emphasize that proceeding was not "in" the civil case but was an independent criminal proceeding growing out of it. U. S. v. Diapulse Corp. of America, E.D.N.Y.1973, 365 F.Supp. 935. Federal Civil Procedure ⚿ 1995

Introduction into interstate commerce of adulterated and misbranded drug products was violation of § 301 et seq. of this title in violation of order for temporary injunction restraining drug company from introducing into interstate commerce adulterated drugs. U. S. v. Schlicksup Drug Co., S.D.Ill.1962, 206 F.Supp. 801. Health ⚿ 328

27. ---- Defenses, contempt proceedings

In criminal contempt proceedings against defendants who violated injunction in action by the United States under this section, defendants were not entitled to show in their defense that officers and agents of the Food and Drug Administration had procured the injunction by alleged fraud perpetrated on the court. Reich v. U.S., C.A.1 (Me.) 1956, 239 F.2d 134, certiorari denied 77 S.Ct. 563, 352 U.S. 1004, 1 L.Ed.2d 549. Contempt ⚿ 61(3); Injunction ⚿ 230(1)

Contempt proceeding by the United States for violation of injunction obtained by the United States under this section prohibiting distribution of defective merchandise in interstate commerce was not subject to the one-year period of limitations provided in the Clayton Act, former § 390 of Title 28, superseded by § 3285 of Title 18. U. S. v. Dean Rubber Mfg. Co., W.D.Mo.1947, 72 F.Supp. 819. Limitation Of Actions ⚿ 11(1)

28. ---- Review, contempt proceedings

Where trial court did not try issue of guilt or innocence but merely passed upon sufficiency of allegations of application for order to show cause why party should not be prosecuted for criminal contempt for violation of injunction against introduction of misbranded drugs into interstate commerce, trial court's denial of application did not constitute an unappealable adjudication of guilt. U. S. v. Sanders, C.A.10 (Okla.) 1952, 196 F.2d 895, certiorari denied 73 S.Ct. 33, 344 U.S. 829, 97 L.Ed. 645. Injunction ⚿ 231

21 U.S.C.A. § 332, **21 USCA § 332**

Current through P.L. 109-57 approved 08-02-05

21 U.S.C.A. § 332

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EXHIBIT 6

21 U.S.C.A. § 375

Effective: [See Text Amendments]

United States Code Annotated Currentness
Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
Subchapter VII. General Authority
Part A. General Administrative Provisions

§ 375. Publicity

(a) Reports

The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

(b) Information regarding certain goods

The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

CREDIT(S)

(June 25, 1938, c. 675, § 705, 52 Stat. 1057; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

HISTORICAL AND STATUTORY NOTES

Effective and Applicability Provisions

1936 Acts. Section effective twelve months after June 25, 1938, see § 902(a) of Act June 25, 1938, set out as a note under § 392 of this title.

Change of Name

The Department of Health, Education, and Welfare was redesignated the Department of Health and Human Services, and the Secretary of Health, Education, and Welfare or any other official of the Department of Health, Education and Welfare was redesignated the Secretary or official, as appropriate, of Health and Human Services, with any reference to the Department of Health, Education, and Welfare, the Secretary of Health, Education, and Welfare, or any official of the Department of Health, Education, and Welfare, in any law, rule, regulation, certificate, directive, instruction, or other official paper in force on the effective date of Pub.L. 96-88, as prescribed by section 601 of Pub.L. 96-88, Title VI, Oct. 17, 1979, 93 Stat. 696, set out as a note under section 3401 of Title 20, Education, deemed to refer and apply to the Department of Health and Human Services or the Secretary of Health and Human Services, respectively, except to the extent such reference is to a function or office transferred

21 U.S.C.A. § 375

to the Secretary of Education or the Department of Education under Pub.L. 96-88, Title III, §§ 301 to 307, Oct. 17, 1979, 93 Stat. 677 to 681. See section 3441 to 3447 and 3508 of Title 20.

Transfer of Functions

All functions of the Federal Security Administrator were transferred to the Secretary of Health, Education and Welfare and all agencies of the Federal Security Agency were transferred to the Department of Health, Education and Welfare by § 5, 1953 Reorg.Plan No. 1, set out in the Appendix to Title 5, Government Organization and Employees. The Federal Security Agency and the office of Administrator were abolished by § 8 of 1953 Reorg.Plan No. 1.

The Food and Drug Administration, which is charged with the administration of this chapter, was transferred from the Department of Agriculture to the Federal Security Agency, to be administered under the direction and supervision of the Federal Security Administrator, by 1940 Reorg.Plan No. IV, set out in the Appendix to Title 5.

LAW REVIEW COMMENTARIES

Anchors away: The Food and Drug Administration's use of disgorgement abandons legal moorings. William W. Vodra and Arthur N. Levine, 59 Food & Drug L.J. 1 (2004).

RESEARCH REFERENCES

Encyclopedias

76 Am. Jur. Trials 341, Snack Food Product Liability.

25 Am. Jur. 2d Drugs and Controlled Substances § 100, Generally; Purpose of Act.

Treatises and Practice Aids

Federal Information Disclosure § 25:1, Federal Agency Publicity.

NOTES OF DECISIONS

Constitutionality 1
Injunction 2

1. Constitutionality

Action of certain governmental agencies in disseminating information warning the public against the use of certain machines, and of a certain treatment for internal cancer, did not deny manufacturer of such machine of due process of law on any theory of lack of a hearing, in view of fact there is no basis for requiring a hearing before information can be disseminated. Hoxsey Cancer Clinic v. Folsom, D.C.D.C.1957, 155 F.Supp. 376.

2. Injunction

Federal court had jurisdiction under section 1331 of Title 28 of action against Secretary of Health, Education and Welfare and against Commissioner of Food and Drug Administration for equitable relief in connection with press releases tending to discredit views of sellers and distributors of health food products. Ajay Nutrition Foods, Inc. v. Food and Drug Administration, D.C.N.J.1974, 378 F.Supp. 210, affirmed 513 F.2d 625.

21 U.S.C.A. § 375

In view of fact that subsection (b) of this section authorizing Secretary of Health, Education, and Welfare to disseminate information as to certain matters was within express scope of duties of the Secretary, and therefore was obviously constitutional, and in view of fact question of constitutionality of such subsection hardly arose since defendants could disseminate such information even without statutory authority, no substantial constitutional question, requiring convening of a three-judge court was presented by plaintiff's action to enjoin governmental agencies from dissemination of circular warning public that plaintiff's cancer treatment had been found worthless so far as internal cancer was concerned. Hoxsey Cancer Clinic v. Folsom, D.C.D.C.1957, 155 F.Supp. 376.

21 U.S.C.A. § 375, **21 USCA § 375**

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